Centers for Disease Control and Prevention National Institute for Occupational Safety and Health

Summary Minutes of the Sixteenth Meeting

May 19-20, 2003

Sixteenth Meeting of the Advisory Board on Radiation and Worker Health May 19-20, 2003

Meeting Held at the Garden Plaza Hotel Oak Ridge, Tennessee

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Executive Summary

The sixteenth meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at the Garden Plaza Hotel in Oak Ridge, Tennessee on May 19-20, 2003. All members were in attendance on the first day, with one member not attending on the second. Others in attendance included staff of various Federal agencies, as well as members of the public. A list of those in attendance is included in the Summary Minutes of this sixteenth meeting. The Summary Minutes of Meetings 11 and 12 were approved with no changes.

Monday, May 19, 2003

OCAS Program Status Report

Mr. Dave Sundin presented the Office of Compensation Analysis and Support (OCAS) Program report through May 16, 2003, providing statistics on cases referred from the Department of Labor (DOL), requests to Department of Energy (DOE) for personal radiation exposure information and response. Additional statistics were provided on claimant interviews, completed dose reconstructions sent to DOL for final adjudication, cases assigned for dose reconstruction, and draft dose reconstruction reports sent to claimants.

Mr. Sundin indicated that a list of additional physicians had been submitted to DOE recently, with more to be appointed shortly.

DOL Program Status Report

Mr. Shelby Hallmark reported that the program is now fully functioning. Approximately 42,000 claims have been received, approximately 8,000 since October, with 12,000 to 18,000 more anticipated by end of September. Mr. Hallmark indicated they were reaching their goals on timeliness, and are continuing outreach measures through site resource centers and traveling resource centers to address needs of people who haven't yet come forward to file claims.

Mr. Hallmark explained under Subtitle D may be available for those not eligible under Subtitle B of the Act, and those claimants are provided with the necessary information to pursue that possibility.

Recent IREP Modifications and Recommended Updates

Mr. Brian Thomas of SENES Oak Ridge, Inc. described four minor updates made to Interactive RadioEpidemiological Program (IREP) on May 1, 2003. They were new minimum latency adjustment functions for leukemia and thyroid cancer; removal of "Total/Annual" pull-down menu from the "Radon Exposure Information" input screen; guidance for selecting specific cancer models and guidance provided for selection of radiation type, or "Help" screens.

Dr. Iulian Apostoaei presented a recommended update in the application of the risk coefficients for thyroid cancer, describing the approach in the newly-updated National Cancer Institute (NCI) version of IREP, rationale for the approach, interpretation of the data, and the effect of the recommendation, concluding with reasons to implement the update.

The UK Compensation Scheme for Radiation Linked Diseases

Mr. Michael Lewis, Executive Secretary of the UK Scheme, presented the background and history of the Scheme, which was created at the end of 1982, and included a description of case processing and Scheme management, as well as the number of claimants processed to date and total amounts paid.

Mr. John Billard, National Secretary with the Trade Union Prospect, offered a comparison of the UK Scheme and Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), and elaborated on the differences and difficulties of choreographing a good working relationship between the employers, trade unions, and Scheme management.

Dr. Andy Slovak, BNFL's Chief Medical Officer, explained that the Scheme's technical basis is based on BEIR V, detailing differences in their approach to dosimetry and probability of causation, including issues they have addressed in the last few years.

Working Group Report - Dose Reconstruction Review Process

Mr. Mark Griffon briefly outlined the issues the work group is addressing and their progress, as well as a description of the Pre-bidder's Conference in late April. Due to time constraints of adhering to the full agenda, and with more time scheduled for the work group, details were postponed until then.

Future Consideration of Uncertainty in IREP

Dr. Owen Hoffman, SENES Oak Ridge, Inc., indicated that the uncertainty in IREP is meant to reflect current state of knowledge; and when knowledge improves, uncertainty should be updated.

He proceeded to present areas where he felt IREP might be updated in the near future, including revised risk coefficients from Japanese survivors, the effects of changes to BEIR VII, re-evaluation of the transfer of risk between populations, exposures at low dose rates, lung cancer and smoking, possible updates to Radiation Effectiveness Factors (REFs) in IREP, and the overall effect of future updates to NIOSH-IREP.

A Refresher and Update on REFs Assumed in IREP

Dr. David Kocher, SENES Oak Ridge, Inc., commenced his presentation by announcing that there had been no changes made since the information he presented last July, nor had there been any clear indication that any gross errors were made. His intention was to highlight issues or areas where future work might be helpful in improving state of knowledge. He reminded the group that REFs are factors in risk equations that take into account uncertainty in our state of knowledge, emphasizing that they're subjective representations of uncertainty. He explained the development of REFs, specifically for neutrons, alpha particles, photons, and electrons, and described issues with each, projecting a possible need to address other radiation types.

NAS Report on Review of DTRA Dose Reconstruction Program

Mr. Dennis M. (Mike) Schaeffer, representing the Dose Reconstruction Program of the Defense Threat Reduction Agency (DTRA) of the Department of Defense(DOD), produced an overview of a report recently released by the National Academy of Sciences (NAS) review of that program following a General Accounting Office (GAO) audit. He described the charges given to the NAS which related to dose reconstructions and to the entire program, and summarized the NAS conclusions for each.

Public Comment Period

Public comment was solicited on both days of the meeting. Public input on the first day included the following:

- Issues related to waiting five years after enactment of the statute to take up worker studies in the NIOSH compensation model.
- Opening the inquiry into probability of causation for Chronic Lymphocytic Leukemia.
- Concerns were expressed about the length of time to complete dose reconstructions, as well as the use of questionable data.
- Difficulty for some claimants to answer the interview questionnaire.
- Completion of the site profile for Mallinckrodt Chemical.
- Destruction of records on workers under Q clearance with DOE.

- Concerns were expressed about claims denied after dose reconstruction and then added to the SEC.
- Concerns were raised about the equity of smoking and lung cancer in the Special Exposure Cohort (SEC).
- Shortening the latency period in bone cancer.

Tuesday, May 20, 2003

Ethics for Special Government Employees

Ms. Paula Kocher, Deputy Legal Adviser in the Office of General Counsel (OGC) for Centers for Disease Control and Prevention (CDC) and similarly the Agency for Toxic Substances and Disease Registry (ATSDR), advised the group that they were to act under two sets of rules, a standard of conduct as a Special Government Employee (SGE) and the rules derived from the Federal Advisory Committee Act (FACA). She described some of the pertinent rules, giving examples of situations and how to handle them. Issues covered included use of non-public information, outside activities, compensation, employment restrictions, and post-employment. She briefly covered the Privacy Act and its implications in the Board's work.

Epidemiological Research of DOE Workers - Status

Dr. David Utterback, Chief, Health-Related Energy Research Branch (HERB) at the National Institute for Occupational Safety and Health (NIOSH), addressed the group on the background of HERB, its mission, funding, methods of study, and staffing. He explained that HERB's research mission is to understand the effect of radiation exposure in the occupational setting. In addition to radiation, the Branch studies chemical and other stressors within the work environment. He described the research goal as evaluating the relationships between workplace exposures and diseases, using and applying the best available analytical methods, to further the NIOSH commitment to protect the health of the American work force.

Dr. Mary Schubauer-Berigan, lead epidemiologist with HERB, Division of Surveillance, Hazard Evaluation and Field Studies (DSHEFS) within NIOSH, spoke about HERB's current epidemiologic research program in the context of issues raised by the Board at the February meeting. She described several cohort studies being conducted through grants, contracts, or cooperative agreements, as well as internal studies. They included Rocky Flats workers, the Hanford cohort mortality experience; radon, cigarette smoking, and lung cancer at the Fernald facility, exposure to high energy photons at the Portsmouth Naval Shipyard, and a large cohort study of more than 60,000

workers at the Idaho National Engineering and Environmental Laboratory (INEEL).

Dr. Schubauer-Berigan then explained the difference between cohort and case-control studies, and described several ongoing case-control studies at various sites.

High priority future research projects were described briefly, as well as some of lower priority. With most DOE facilities moving from production into a decommissioning and decontamination era, it is believed that studies of hazards of health effects faced by these workers is an important future direction.

HERB's interpretation of the Board's priority items decided upon at the February 6-7, 2003, meeting were outlined, as well as plans to address those concerns in the future.

Board Discussion/Working Session

Review Process of Completed Dose Reconstructions

Mr. Mark Griffon presented the Board with three documents in addition to the three presented earlier and described the purpose for each. Because the contract is anticipated to be awarded in September, it was decided by the Board that the members should take the time to review the documents in detail prior to the next meeting at which time they could present their opinions and move to a decision and a final draft.

Public Comment Period

Public comment was solicited on both days of the meeting. Public input on the second day included the following:

- An appeal for fairness in the system.
- A concern for dose monitoring and preservation of records for workers involved in the current decommissioning and decontamination activities.
- A concern was expressed regarding "an organizational disconnect" between the occupational safety program and the needs for epidemiological research, specifically continued funding.
- Issues surrounding missing employment records.
- A question regarding adding additional sites to those that are compensable for silicosis.
- The scarcity of physicians available to claimants under Subtitle D.

Non-Agenda Item

Mr. Larry Elliott made an appeal to the Board for their thoughts on permitting the use of Oak Ridge

Associated Universities (ORAU) personnel with dose reconstruction experience at the Mound, Ohio site in furthering the completion of pending cases.

The idea met with strong opinions on both sides of the issue. With no clear consensus, it was suggested that public comment on the question be taken.

The following public comments were provided:

- Make the question an agenda item at the next meeting.
- Is the conflict of interest screening adequate.
- Expand the pool of qualified personnel.

Review and Approval of Draft Minutes, Meetings 11 and 12

A motion to approve the executive summary and the minutes of the eleventh meeting was seconded and unanimously passed.

A motion to approve the summary report of the twelfth meeting was seconded and unanimously approved.

ABRWH Schedule and Future Agenda Items

A motion for the Board to meet in Cincinnati on August 18, 19 and, if necessary, 20 was seconded and unanimously approved.

Action will be taken on the materials provided by the Dose Reconstruction Review working group. A status report on site profile progress was requested.

Housekeeping and Miscellaneous

- Ms. Corrine Homer requested that members provide, by e-mail, their time to Mr. Larry Elliott for approval, separating working group and regular meeting time.
- It was suggested that members provide their calendars through November to Ms. Corrine Homer in an effort to plan a fall meeting.
- Mr. Robert Presley gave instructions to those members participating in the tour.

With no further business posed, the meeting was officially recessed at 1:50 p.m.

End of Executive Summary

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The Advisory Board on Radiation and Worker Health National Institute for Occupational Safety and Health Centers for Disease Control and Prevention

Summary Minutes of the Sixteenth Meeting

May 19-20, 2003

The Sixteenth Meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at the Garden Plaza Hotel in Oak Ridge, Tennessee on May 19-20, 2003. The meeting was called by the Centers for Disease Control and Prevention's (CDC's) National Institute for Occupational Safety and Health (NIOSH), the agency charged with administering the ABRWH. These summary minutes, as well as a verbatim transcript certified by a court reporter, are available on the internet on the NIOSH/Office of Compensation Analysis and Support (OCAS) web site located at www.cdc.gov/niosh/ocas. Those present included the following:

<u>ABRWH Members:</u> Dr. Paul Ziemer, Chair; Dr. Henry Anderson; Dr. Antonio Andrade; Dr. Roy DeHart; Mr. Richard Espinosa; Mr. Michael Gibson; Mr. Mark Griffon; Dr. James Melius; Ms. Wanda Munn; Mr. Leon Owens; Mr. Robert Presley; and Dr. Genevieve Roessler.

Designated Federal Official: Mr. Larry Elliott, Executive Secretary

Federal Agency Attendees:

Department of Health and Human Services:

Mr. Steven Ahrenberg, Mr. Todd Braswell, Mr. Russ Henshaw, Mr. Stu Hinnefeld, Ms. Cori Homer, Ms. Liz Homoki-Titus, Dr. John Howard, Mr. Ted Katz, Mr. David Naimon, Dr. Jim Neton, Dr. Mary Schubauer-Berigan, Mr. David Sundin, Dr. David Utterback, and Mr. James Yiin.

Department of Labor:

Mr. Shelby Hallmark and Mr. Peter Turcic

Department of Defense:

Mr. Dennis M. Schaeffer

Guests and Members of the Public:

Tim Adler (ORAU, Oak Ridge, TN); A. Iulian Apostoaei (SENES, Oak Ridge, TN); R.L. Ayers

(Oak Ridge, TN); Wm. L. Beck (ORAU, Oak Ridge, TN); Glenn Bell (Beryllium Victims Alliance, Oak Ridge, TN); John Billard (PROSPECT, United Kingdom); Rhonda Bogard (Y-12, Oak Ridge, TN); Denise Brock (U.N.W.W. of St. Louis Region, Moscow Mills, MO); Gina Broome Den Est an Zach Wamp, Oak Ridge, TN); Julia DeHart (Nashville, TN); Phillip Foley (PACE, Symsonia, KY); Sally Gadola (ORAU, Oak Ridge, TN); Jeff Hill (ATLC ESOH REP); Jennifer Hoff (ORAU, Fort Thomas, KY); Owen Hoffman (SENES, Oak Ridge, TN); Karin Jessen (ORAU, Oak Ridge, TN); David Kocher (SENES, Oak Ridge, TN); Bruce Lawson (PACE, Oliver Springs, TN); Jacob Howard Lawson (ATLC/BWXT-Y12, Oak Ridge, TN); MD Lewis (BNFL, United Kingdom); Patrick C. Lowery (REACTS, Oak Ridge, TN); Fay M. Martin (CAP/LOC, Oak Ridge, TN); Richard Miller (GAP, Holyoke, MA); Herman Potter (PACE); Steve Powell (Titan, Reston, VA); Louise S. Presley (Clinton, TN); Carl Scarbrough (ATLC, Oak Ridge, TN); D.M. Schaeffer (DOD/DTRA, Alexandria, VA); Jane Schalenter (Senator Alexander, Knoxville, TN); Andy Slovak (BNFL, United Kingdom); Michael L. Soulevrette (BWXT Y-12, Oak Ridge, TN); John Stewart (PACE, Oliver Springs, TN); Bob Tabor (FAT&LC, Harrison, Ohio); Bill Tankersley (ORAU, Oak Ridge, TN); Brian Thomas (SENES, Oak Ridge, TN); RE Toohey (ORAU, Oak Ridge, TN); Albert Wiley (REACTS/ORAU, Oak Ridge, TN); Marilyn Ziemer (Lafayette, IN).

Monday, May 19, 2003

Opening Remarks

Call to Order/Welcome

Dr. Paul Ziemer called the meeting to order at 8:30 a.m., welcoming the attendees. He reminded everyone to register their attendance each day at the registration table located in the back of the room, and instructed members of the public to sign up if they wished to address the Board during the public comment periods.

Announcements

Dr. Ziemer introduced a special guest of the Board, Dr. John Howard, Director of the National Institute for Occupational Safety and Health (NIOSH). Dr. Howard expressed his appreciation to the Board for their work. He complimented the Board on their dedication and professionalism, and offered his assurance that the Board had the full support of the Institute and its leadership, as well as that of the Department of Health and Human Services (DHHS).

OCAS Program Status Report

Mr. David Sundin
Deputy Director, NIOSH/OCAS

Mr. Dave Sundin reported on NIOSH's Office of Compensation Analysis and Support (OCAS) Program through May 16, 2003. To date, close to 13,000 cases have been referred to NIOSH from the Department of Labor (DOL). The initial contact letter to the claimant has been modified to include the name of a public health advisor who is available to provide specific information on their claim. It also introduces and explains Oak Ridge Associated Universities' (ORAU's) role in the process and provides the ORAU toll-free phone number.

Approximately 12,000 requests for personal radiation exposure information have been sent to Department of Energy (DOE) points of contact, with responses received to 63 percent of the requests. About 20 percent of requests are more than 60 days outstanding. These cases are highlighted in a periodic e-mail status report sent to each DOE point of contact and the DOE Office of Worker Advocacy.

Interviews have been conducted with more than 2,600 employees and survivors. The number of

completed dose reconstructions returned to DOL for final adjudication stands at 73; 300 cases have been assigned for dose reconstruction, and draft dose reconstruction reports have been sent to claimants in 137 cases.

As OCAS receives more and more claims, the number of phone calls received increases, currently approximately 80 per day, with responses provided to nearly 30,000 since October of 2001. The web site continues to be an active source of information. Over 1,600 claim-related e-mails have been received, with the goal of responding within 24 hours to each one.

On April 4, 2003, the Memorandum of Understanding between DOE and HHS was signed by the Deputy Secretaries of those Departments and is available on both the DOE and HHS-OCAS web sites for review.

Public comment period for the proposed rule for adding classes of employees to the Special Exposure Cohort (SEC) closed on May 6, 2003. In addition to the Board's comments, the Docket Office received comments from 16 other groups and individuals. All those comments are now being considered.

Transmittal of a list of 33 additional physicians to DOE brought the number of appointed physicians to nearly 80, with 30 more to be appointed shortly.

In late March, OCAS approved a Technical Basis Document for developing an exposure matrix for the Bethlehem Steel Corporation, use of which will permit completion of virtually all the roughly 435 claims from that company. This document is also available on the OCAS web site.

OCAS currently has 35 employees in Cincinnati, with three support staff members in Atlanta and Washington, D.C. Recruiting efforts continue to fill a few remaining vacancies. Presently, ORAU has 170 full-time equivalents on their staff. Under the ORAU contract, production goals were negotiated as part of the plan to reduce the backlog of claims awaiting dose reconstruction. The plan calls for completion of nearly 6,000 draft dose reconstruction reports this year through developing a capacity to produce a minimum of 200 dose reconstructions weekly by July.

Discussion Points:

Dr. James Melius asked how claimants were informed of delays in receipt of replies to information requests to DOE, if claimants were notified of delays, and that claimants deserved communication.

Mr. Dave Sundin replied that the claimants are told that targeted response time is 60 days, but not all sites respond at the same rate. Claimants can be told how many days their request has been with DOE, if any response has been received, what is known about a particular site. Some information on the web site addresses the issue, but site response profiles are not provided. Questions are handled on a case-specific basis.

- Mr. Larry Elliott agreed with Dr. James Melius, and indicated that those groups were being targeted and the communication vehicle to use for those groups was being developed. He pointed out that those callers are a minority in the claimant population, but that contact and dialogue needed to be maintained and the issue was being addressed.
- Dr. Antonio Andrade cautioned that, while he agreed communication was important, oversimplified communication could be misleading.
 - Dr. James Neton pointed out that because claimants are contacted prior to the interview, are then interviewed, then receive a follow-up summary of the interview, they are being communicated with. Additionally, with the computer-assisted telephone interview (CATI) system getting into full swing, ORAU can now conduct approximately 1,000 interviews per month, so many of the early claimants will be contacted in the near future directly by NIOSH.
- Dr. Roy DeHart questioned if the goal of 6,000 completed dose reconstructions by the end of the year is realistic.
 - Mr. Dave Sundin responded that he felt it was, due to the groundwork put in place to permit those kinds of goals to be achieved, and pointed out that the goals were developed in consultation with ORAU.
- Mr. Robert Presley asked for an elaboration on records problems with the Oak Ridge site. Mr. Dave Sundin responded that with a high volume of requests, the number of severely late cases was not huge and that Oak Ridge had been very responsive.
- Mr. Mark Griffon inquired on the progress of site profiles and asked if a status report could be provided by the end of the meeting.
 - Dr. James Neton advised that a draft site profile had been completed for the Savannah River Site and was being reviewed by staff. Others are being developed, but the issue of sequence of site profile development is not ready for discussion at this meeting.
- Mr. Mark Griffon expressed a concern that the targeted 6,000 completed dose reconstructions not cause use of suspect dosimetry data, and site profiling is necessary to test the adequacy of dosimetric records.
 - Dr. James Neton responded that dosimetry information is never taken at face value.
 - Dr. Paul Ziemer asked if a presentation on site profile status might be available at the next meeting
- Dr. Henry Anderson asked for information on a secondary strategy for records requests at the 150-day-plus mark. At what point do you need to go into a secondary strategy?
 - Mr. Dave Sundin agreed that there was no need for endless searches with no prospect of finding information, and it is believed sites are on productive searches or indexing strategies that will yield information. No response has indicated all search strategies have been exhausted with no results, nor has the question been asked of DOE at this point.
- Dr. James Melius noted that it looked as if half of the conflict of interest statements were missing on the web site.
 - Dr. Richard Toohey replied that the form had been changed and they had now all been received and were being scanned to go onto the web site. He pointed out that the information would be available only on personnel directly involved in dose reconstructions.

DOL Program Status Report

Mr. Shelby Hallmark Department of Labor

Mr. Hallmark announced that, having worked out all the relationships with NIOSH, DOE, the Department of Justice, and all the other ancillary parties, the Program is now fully functioning. DOE was responding more quickly to requests for records and the entire system is working more effectively.

DOL has received approximately 42,000 claims, and Mr. Hallmark noted that a case could include multiple claims, and that somewhat over \$562 million has been paid out, with over 300 Federal and contractor workers involved in sites around the country. From 12,000 to 18,000 additional claims are expected to be received by the end of the year. Of the total 42,000, approximately 57 percent are survivor claims. Mr. Hallmark reported that the number of claims pending had dropped to 3,000, which are primarily new cases received in the last few months.

It was noted that only about \$10 million of the \$562 million paid out was for medical benefits, indicating that people are apparently not making claims for those benefits. There have been approximately 11,000 denials for not covered claims, claims that should have been filed under Subtitle D, a figure which tends to skew the outcomes.

DOL has set timeliness goals of 120 days for straightforward cases and 180 days for the more complicated cases where a records search is involved. Those goals have been reached on average, now standing at 113 and 178 days respectively.

As it relates to the goal of 6,000 dose reconstructions by the end of the year, DOL has set a target of completing the first stage, the recommended decision level, in three weeks of receipt of the case from NIOSH. Because they anticipate getting "clumps" of cases due to the site profile approach, cases will be moved around geographically as necessary among the four offices -- Seattle, Denver, Cleveland, and Jacksonville -- to distribute the workload and move the case through promptly.

DOL anticipates there are claimants who could file but who have not, so their outreach program is continuing, including resource centers located at sites, as well as traveling resource centers, working with unions, media, and public service announcements in an effort to reach potential claimants who may no longer be affiliated with unions or communities or other activities. They are continuing to look for ways to improve outreach to assure that everyone eligible for the program comes forward.

Discussion Points:

- Dr. Roy DeHart asked for an explanation of Subtitle D, and specifically if it included mechanical injuries. Mr. Shelby Hallmark responded that Subtitle D included occupational illnesses caused by exposure to toxic agents, but not things such as hearing loss or mechanically-conceived injuries. He pointed out that individuals eligible under Subtitle B are also eligible to apply under Subtitle D. He noted that when a claim is received erroneously filed under Subtitle B; the claimant is informed of the Subtitle D option.
- Dr. James Melius asked for an accounting discrepancy in completed cases sent to DOL. Mr. Larry Elliott responded that they had been signed and sent on the preceding Friday and that there is some lag time from one point to the other.
- Dr. James Melius asked if the SEC claims were trending up or down. Mr. Shelby Hallmark replied that the information he receives weekly is not broken down by site, so he didn't have that information.
- Dr. James Melius asked if there was a system in place to track claims received initially as an SEC claim, but where the claimant failed to meet some portion of the requirements. Mr. Pete Turcic with DOL responded that the claims are tracked and sent to NIOSH for dose reconstruction.
 - Mr. Larry Elliott noted that they were discussing two different types of claims, both of which can be and are currently being tracked. One is an employee of an SEC site with a non-presumptive cancer claim; the other is a claimant with less time employed at an SEC site than required, but who may have worked at other sites.
- Mr. Mark Griffon asked if statistics were available on types of cancers overall and then broken out by site, and if job categories were tracked.
 - Mr. Shelby Hallmark responded that the former was available and would be provided to the Board, but the latter was not an element of their data system.

Recent IREP Modifications and Recommended Updates

Recent Modifications

Mr. Brian Thomas SENES Oak Ridge, Inc.

Mr. Brian Thomas announced the four changes he would describe were very recent. The minimum latency adjustment functions for leukemia and thyroid cancer presented in October and March by Mr. Russ Henshaw had been implemented. The previous version assumed minimum latency periods of two and three years respectively, with no uncertainty assigned for that minimum latency period, thus a zero probability of causation. The revised latency periods result in non-zero risk for all times since exposure, with no decrease in probability of causation in any of the time since exposure compared to the previous version.

The previous version of Interactive RadioEpidemiological IREP featured a pull-down menu when entering exposure information for someone exposed to radon, allowing the selection of total or

annual. Since total was never used, the pull-down menu was removed and the user is required to enter exposure on an annual basis. This ensures the latency period for lung cancer is properly accounted for, in addition to simplifying the input screen.

A "Help" button has been added to the primary input screen guidance for the cancer model pulldown menu. It provides a link to the tables put together by NIOSH which can download the entire NIOSH-IREP technical documentation, including Table 4, cancer models for primary cancer sites; and Table 7 if only the secondary cancer site is known.

A second "Help" button has been added to give guidance on which radiation type to select. This is for the benefit of the public who may access the site and want to look through those items. The help file includes important distinctions between internal and external exposures.

Recommended Updates

Dr. Iulian Apostoaei SENES Oak Ridge, Inc.

The first recommendation related to the latency period for bone cancer, which is currently assigned the same value as all solid tumors of about ten years. Recent research indicates the latency period should be lowered to perhaps five years. This would be a claimant change, producing risk at shorter times after exposure.

The second recommendation concerned application of risk coefficients for thyroid cancer, which presently -- at ages less than 20 -- are reduced by a factor equal to the radiation effectiveness factor for x ray. This risk coefficient was obtained from a pooled analysis of children and adults exposed to x rays and gamma rays. The risk coefficients for children are dominated by studies of patients exposed to x rays and for adults by exposure to gamma rays, the A-bomb survivor studies. Believing that x rays are more effective in inducing thyroid cancer than high energy gamma rays, the risk coefficients for children were reduced by a factor equal to their effectiveness factor.

Further study revealed no important difference between the risk coefficients from exposure to x rays and exposure to high energy gamma rays when individual components were pooled. The conclusion was that a good surrogate for the risk coefficient would be those from exposure to high energy gamma rays and it is recommended to remove the reduction factor for exposures at less than age 20.

Application of the update would result in no change in the risk coefficients for exposure in adults. The risk coefficient for age at exposure of 15 to 19 will increase, and will show a continuous decrease with age at exposure. The recommendation would have very small impact on the total number of claims, but is claimant-fluorible for age at exposure under 20.

Dr. Iulian Apostoaei indicated the proposal is scientifically defensible and has already been

approved by the National Cancer Institute (NCI) and implemented in their version of IREP.

Discussion Points:

- Dr. Genevieve Roessler questioned how many people would be affected by the recommended update related to thyroid cancer. Dr. Iulian Apostoaei replied that while the number would be very few, the cutoff age is 15.
- Dr. Paul Ziemer wondered whether the Board should go on record as being supportive of the update, as it had in the previous update. Mr. Larry Elliott replied that it was being taken into consideration by NIOSH and they were conferring with NCI, although there were no claims relevant to the change. He indicated it would be again brought to the Board for deliberation if NIOSH determined it was something that should be done.
- Dr. James Melius asked where NIOSH stood with regard to the bone cancer proposed update. Mr. Larry Elliott indicated that while Dr. James Neton and others may have been aware of the bone cancer modification, he had just learned of it. NIOSH is in concert with NCI as much as possible and will bring matters to the Board when appropriate. Mr. Larry Elliott reminded the Board that these items were presented for informational purposes at this
- Dr. Antonio Andrade inquired as to the size of the cohorts which had produced the new
 - Dr. Iulian Apostoaei responded that the exposure of children to x ray studies included tens of thousands, with very few children in the A-bomb survivor studies, with the reverse being true in adults.

The UK Compensation Scheme for Radiation Linked Diseases

Mr. Michael Lewis Executive Secretary, UK Compensation Scheme

By way of background and history of the UK Compensation Scheme, Mr. Michael Lewis indicted the legal basis is the Nuclear Installations Act of 1965 which required licensing of nuclear sites and makes license holders responsible for any harm to its employees arising from site operations, negligence not required to be proven. Compensation was awarded through court action, proving lengthy and expensive, traumatic for families concerned, and with most claims settled out of court. While license holders, unions and claimants had concerns from their own perspective, the common thread was a desire for a workable alternative, agreeing that it must be faster, less costly, more generous and less traumatic.

Thus the Scheme was introduced in 1982, a non-compulsory agreement between the employers and unions, in order to facilitate compensation for injuries suffered as a result of radiation linked diseases, using probability of causation methodology based on an excess absolute risk model (ICRP-

26).

Initially accepting mortality cases only, the Scheme was reviewed in 1986 and deemed successful and eligibility was expanded to include morbidity. The probability of causation methodology was supported by National Institutes of Health (NIH) probability of causation tables (1985) and Nuclear Regulatory Commission (NRC) review (1984). That basis was revised following BEIR V (1991).

Case processing involves eligibility, screening, a factual report, case determination, and payment based on the UK legal concept of quantum, which is a full payment amount upon which a fractional determination is made based upon circumstances of the claim.

One of six schedules or dose risk models are assigned, which is the basis for the calculation of probability of causation. A probability of causation of less than 15 percent fails the screening process. A probability of causation from 20 to 30 percent results in a payment, if awarded, of 25 percent of the quantum amount and increases on a sliding scale, with up to 50 percent or more probability of causation being awarded full quantum amount. A small number of cases where special factors apply and where schedules may be confused or confounded are referred to an expert panel for determination.

Payments are calculated exactly as they would be through the UK legal system, and quantum is determined by legal negotiations, not the Scheme. Time from application to completion of the process is based on an agreed time scale of nine months for failed cases and 12 months for cases passed for payment. The components of the time scale are six months to issue screening data, at which point the claimant would know whether they would receive payment or not. Claimants may challenge or raise concerns at that point. The unions then have three months to respond to screening data if the case fails or one month if it passes. The factual report is prepared within three months by the employer, agreed within one month by the union, and then determination of payment.

Since the Scheme is not compulsory, legal action may still be taken, although the Scheme requires a stay of legal action during the processing period. Claimants receiving compensation are asked to sign an agreement that they will not pursue legal action on the claim for which they have been compensated. Failing claims may proceed with legal action. All participants are bound by the principle of the Scheme, with workers having the generosity of the Scheme available to them and the Unions not supporting any claim through the courts which would more appropriately be handled through the Scheme.

To date the Scheme has handled approximately 1,100 applications with 50 to 60 ongoing. A total of 94 claims have resulted in payment, with 66 made at less than full quantum. Total amount of awards has been roughly £5 million or \$8 million.

Each employer or historical group of employers has a Compensation Scheme Management Board, managing issues pertaining to those particular employers. They are established by the unions and the employer signing a morbidity and mortality agreement. The employer provides dosimetry protocols which are vetted by the Technical Working Party and endorsed by both employers and unions on the Management Board, and each Management Board has its own internal procedures for dealing with claims.

Management Boards nominate one management representative and two union representatives to sit on the Scheme Council, which makes sure that the Scheme operates consistently across the employer groups. The Council meets annually and is chaired by the British Nuclear Fuels (BNFL) UK Management Board chair, and is advised on technical matters by the Technical Working Party.

Mr. John Billard Prospect and Scheme Unions

Mr. John Billard pointed out that the UK Scheme is an alternative to legal action. As a collective agreement with the employers in the UK, their agreements are not legally enforceable, but are "Binding in Honor" between the parties. While nothing would prevent one party or the other from walking away, it is generally recognized that failure to honor the agreements could have far-reaching consequences.

As an alternative to a lengthy process, it is essential that everyone taking part in the Scheme has confidence in what is being done on their behalf. Since claimants are seeking to make a direct link between employment in the nuclear industry and their disease, and since nine out of ten times in the UK Scheme their claims fail, claimants have to be satisfied the Scheme is operating under the latest scientific and medical knowledge. The unions have to be able to say they have confidence in the outcomes. That confidence has led employers to join the Scheme.

While the history of the nuclear industry has always been in the public sector, much of that is now being operated by the private sector, as will the decommissioning task expected to go on for another 50 to 80 years, and those private sector employers are required to join the Scheme. They have to share the same confidence as the unions, because it will become private sector money which may be paid in compensation.

Mr. John Billard finds the SEC to be very close to what they have been trying to do for 20 years, and there are many union members in the UK who would like to see that concept implemented. However, they feel it would be impossible to persuade an employer to join such an arrangement because there is no government money involved in the operation of the Scheme.

Dr. Andy Slovak Chair, Technical Working Party

Dr. Andy Slovak compared the differences and similarities in the UK Scheme and the US Program, particularly highlighting the UK's seven dose models as compared to 34. He noted a number of

differences in the approach to dosimetry, primarily using statutory dose records and some reconstruction, and the use of the 50th percentile rather than a 99 percent confidence interval. The Scheme also has some cancers which are specifically non-eligible. He pointed out that some aspects of BEIR V had been adjusted to provide some level of built-in generosity to claimants, citing the spirit of choosing to err on the side of benefiting claimants as another similarity.

He described the Technical Working Party as a forum wherein any party may raise a scientific issue. It is the responsibility of the Technical Working Party to respond with what is seen as the technical scope, which is then either agreed upon or they're asked to conduct another review. Anyone may attend who is representing one of the parties, and all input is considered in. Some issues addressed over the last few years include non-uniform neutron dose and an update of site histories.

Dr. Andy Slovak indicated he believed a primary technical issue on the horizon is the benefit of having some level of formal interchange with the Program at a scientific level. They, in the future, are looking forward to the release of the new NIH tables. He believes a difficult issue to be faced in both the UK and the US will be non-cancer outcomes associated with radiation dose in A-bomb survivors

He concluded by saying that the Scheme has demonstrated over its 20-plus years that it enjoys continued support from the employers, the unions and the scientific community as supported by its extension throughout the UK nuclear sector.

Discussion Points:

- Dr. Genevieve Roessler inquired if the UK Scheme had a team ready to evaluate BEIR VII and make adjustments, if necessary. Dr. Andy Slovak responded that was very much in focus, but his successor would be doing it.
- Ms. Wanda Munn wondered whether the Scheme experience with the UK equivalent of DOE work force was different than with the commercial work force. Mr. John Billard noted that it had been made an objective that private sector employers coming into the industry would join or be part of the Scheme. He highlighted the point that the Scheme never closes a case so that in the event of a development in medical or scientific knowledge, the case would be reopened if there's a chance of a settlement.
- Dr. Antonio Andrade asked what would happen if there were a criticality event with no criticality dosimetry involved, yet several witnesses to the fact since bioassay or dosimetry records are needed to follow up on a particular case for the Scheme. Mr. Michael Lewis responded that they would look toward the employer's technical people to make an assessment of the potential doses to individuals involved in the incident and the assessment would be placed on record within the Scheme. Mr. Michael Lewis also noted that something not mentioned in the presentation was that the Scheme runs by consensus.

- Mr. Mark Griffon asked whether the Scheme operation included a claimant interview. Mr. Michael Lewis indicated that an interview was conducted only when a claimant raised specific issues and that out of 1,000 claims, they have arranged less than a dozen meetings between claimants, a union representative, and technical representatives from the employers.
- Mr. Larry Elliott wondered whether transparency was a difference between the Scheme and the Program. Mr. Michael Lewis declared it more of a cultural difference between the US and the UK.
- Dr. Roy DeHart asked if the Technical Working Party had ever found it necessary to use any external quality assurance measures or assessments. Dr. Andy Slovak indicated they'd never done so
- Mr. Shelby Hallmark of DOL inquired why, since there was a successful strategy for resolving disputes, the expert panel was needed to resolve really difficult disputes. Dr. Andy Slovak replied that the expert panel was set up at the Scheme's inception to satisfy issues of trustworthiness, reliability and external peer review. With experience, the role of the expert panel has narrowed, but it's still found useful to have a second opinion on really tough issues. And because the panel is made up of very distinguished scientists, they often will raise issues when they feel the Scheme is not clear about what it's doing. Mr. Michael Lewis pointed out that the panel exists to consider those cases where the schedules don't give a particularly reliable answer for all sets of circumstances.
- Mr. Shelby Hallmark asked what the impact would be on the confidence issue in the UK if the success rate is higher through the NIOSH process. Dr. Andy Slovak remarked that they would be quite concerned if large differences appeared, probably presenting the most problems for the unions, but if there are problems, they will have to address them. Mr. John Billard agreed, adding that he was reasonably confident there wouldn't be those difficulties. Mr. Michael Lewis noted that it would also depend on how the dose profile of the Program claimant population compared to that of the Scheme.

Working Group Report - Dose Reconstruction Review Process

Mr. Mark Griffon Dose Reconstruction Review Process Workgroup

Mr. Mark Griffon advised the audience that the working group has been established to look at the Board's role in reviewing the NIOSH dose reconstruction activities in that the Board is statutorily required to review the scientific validity and quality of NIOSH dose estimates and dose reconstruction efforts. The intent is to look at individual dose reconstructions reviews, site profile and worker profile reviews, SEC petition reviews, as well as a review of NIOSH procedures.

To that end, the Board has initiated activities to obtain, with NIOSH's help, a contractor to assist the Board in doing those reviews. NIOSH recently held a pre-bidder meeting where members of the working group entertained questions from potential bidders. Those bids were due on June 2, 2003,

and it is hoped to have a contractor in place by early September.

The working group is in the process of developing draft procedures for the review process, case selection, and developing individual task orders. Thus far basic and advanced case review procedures have been drafted, with a focus on individual case report forms. It is envisioned the contractor will write a report for individual reviews, in addition to a summary report on a group of cases which will then be presented to the full Board. On individual case reviews, the working group is developing a method whereby Board members would rotate in for work with contractor staff. The last item would be the Board report form which the Board would then forward to HHS.

Mr. Mark Griffon indicated the working group would meet again that evening to address a number of issues still in the "how-to" stage, and would report to the Board tomorrow with more information and the remainder of the draft forms

Certificate Presentation

Dr. John Howard Director, NIOSH

Dr. John Howard presented Ms. Sally Gadola, an original member of the Board, with a certificate in recognition and appreciation for her service on the Board.

Ms. Sally Gadola replied that her service had been an honor and a privilege, remarking on the people she'd met, reminding the Board what important work they're doing, and encouraging the Board and NIOSH to continue doing so.

Future Consideration of Uncertainty in IREP

Dr. Owen Hoffman, SENES Oak Ridge, Inc.

Dr. Owen Hoffman reported that the methodology being used in the Interactive RadioEpidemiological Program (IREP) is derived from that employed in the Oak Ridge health studies from 1995 to 1998 and differing from the application in the UK Scheme in one major area, the full disclosure of uncertainty in a quantitative manner.

Lung cancer and cigarette smoking was pointed to as an area where there are active efforts by NCI to update IREP based on new information which has developed in from the follow-up of the A-bomb survivors. The impetus for this revision has come from a paper published this year by Don Pierce and colleagues at the Radiation Effects Research Foundation. A prime envisioned update will be the revised risk coefficients from the Japanese survivors. Also expected are improved statistical methods of dose response analysis.

Within the worker community there has been concern that the sole basis of risk estimates has come from the Japanese cohort, yet there are many studies on worker cohorts not included in the IREP program. Perhaps in the near future there may be efforts undertaken to combine datasets. Another area would be a re-evaluation of the assumptions used in transferring risk between the Japanese cohort and the U.S. populations. An area of interest in changing assumptions within IREP has to do with the assumption on the low dose and dose rate effectiveness factor. Recent data on cohorts exposed to fractionated and chronic external radiation and chronic exposure to internal emitters may substantially update current knowledge.

Because of uncertainties in epidemiology and uncertainties in dose reconstruction for those cohorts, distinctions within a factor of two will be difficult to make. New mechanistic information from recent low dose investigations with cellular and complex biological systems might add some light to the interpretation of new epidemiological datasets.

Dr. Owen Hoffman anticipates there may be a reduction in the overall uncertainty distribution in IREP for the low dose and dose rate effectiveness factor and a possible decrease in the central estimate, whereby every decrease in the central estimate would result in an increased risk, and every increase in the risk per unit dose would result in an increase in the probability of causation.

In looking at the overall effect of future updates into NIOSH-IREP, Dr. Owen Hoffman pointed out that placing a decision criterion for eligibility of compensation claims at the upper 99th percentile of probability of causation rewards for uncertainty. If improved state of knowledge decreases the uncertainty but has no effect on the central estimate, fewer claims would be awarded.

Conversely, additional claims may become eligible by updating state of knowledge if the central value of risk increases as a result of modifications or if the upper range of uncertainty increases. He would expect that to occur if other cohort datasets were allowed to be used to complement the Japanese survivors in quantifying the original epidemiological data for excess relative risk.

Discussion Points:

- Dr. Genevieve Roessler asked what factors outside the Pierce study, did Dr. Charles Land take into consideration in making his recommendation to NIH. Dr. Owen Hoffman replied that it was the information for other solid tumors that adds extra weight to the justification for the update.
- Dr. James Melius wondered how to get an ongoing effort started to look at ways to utilize work population studies in IREP. Dr. Owen Hoffman indicated that when quantifying state of knowledge all available evidence should be taken into account. Currently the Japanese data is the gold standard, but at some future date other datasets could be brought to bear for a

more complete expression of state of knowledge within the uncertainty estimates. How to do it is up to NIOSH, the Board, and HERB to undertake. And maybe some of this will be forthcoming within BEIR VII. Mr. Larry Elliott added that NIOSH is waiting to see what the BEIR VII committee does. Depending on what their final report says, a decision will have to be made. BEIR VII is likely to be completed mid to late 2004.

- Dr. Antonio Andrade inquired if Dr. Owen Hoffman was aware of the population used in the Pierce data. Dr. Owen Hoffman indicated it was a fraction of the cohort on the order of 30 percent.
- Dr. James Melius inquired of Mr. Larry Elliott his thoughts on addressing the smoking issue. Mr. Larry Elliott replied there had been three-way communication between NIOSH, SENES, and NCI. No lung cancer cases have been finalized where a smoker was found to be non-compensable. While NIOSH is interested in the Pierce paper, it is only one paper. NIOSH is considering it and thinking through what they see. There is a lot of legwork to be done before bringing it to the Board. Dr. Antonio Andrade noted that his question had been intended to put into context the fact that when dealing with probabilistic analysis, only when you have sufficient prior distribution do you feel comfortable about your results.

A Refresher and Update on REFs Assumed in IREP

Dr. David Kocher, SENES Oak Ridge, Inc.

Dr. David Kocher stated his intention to give a broad overview to a difficult subject rather than a detailed technical presentation as he had done last year. He emphasized that REFs are subjective representations of uncertainty and are used to put biological effectiveness on a common scale for all radiation. REFs have been developed for neutrons, alpha particles, photons and electrons. In discussing biological effectiveness, a reference radiation is required, the baseline for which you assume the effectiveness is unity and everything else is relative to that. The IREP reference radiation is high energy photons delivered acutely because that is the radiation to which the A-bomb survivors were exposed and is the source of almost all the data on radiation risks used in IREP to calculate probability of causation.

Many experts have reviewed the radiobiological data which produced Relative Biological Effectiveness (RBE). Thousands of experiments have measured RBE for various endpoints, various organisms, various kinds of radiation. This information has been extensively reviewed, so these reviews were relied upon. They did not come up with probability distributions on the data, however. Dr. David Kocher looked at the summaries and evaluations of data to derive subjective probability distributions.

Most of the data came from studies in small mammals. There is very limited data on humans to address questions of biological effectiveness of different radiations, making the key the use of

judgment in applying available data on RBEs for a variety of systems and biological endpoints.

Beginning with neutrons, studies in mice present clear evidence that there's a difference in biological effectiveness if the endpoint is solid tumors versus leukemias, so separate probability distributions were developed for those two types of cancers. The REF is generally less for leukemia.

There is indication from studies and calculations that the REF for neutrons depends on the energy. Also included in the calculation is a small increase in the REF for solid tumors or leukemias and at any energy under cases of chronic exposure, accounting for the inverse dose rate effect. If the same dose is delivered in two cases, one acutely and one chronically, there is some evidence that response is higher with the chronic dose. The biological effectiveness goes up as the dose goes down, with a small correction of about 40 percent on average for chronic exposures.

With alpha particles there are separate distributions for solid tumors and leukemias based on some evidence that the REF is substantially higher for solid tumors. The REF is not energy-dependent. It's the same for all energies and the only concern was with alpha particles from radioactive decay, which vary over a narrow energy range, roughly 4 to 8 MeV. One of the real areas of challenge is that alpha particles in leukemias are one of the areas on which there is potentially relevant information from studies in humans. There were three sets of information, two of which were on humans (Thoratrast patients and radium dial painters), and were directly contradictory. The third set of information had to do with fission neutrons being roughly the same as alpha particles in terms of biological effectiveness.

A subjective weight was given to each as being plausible -- 50 percent for Thoratrast patients, 25 percent for the other human populations and 25 percent for fission neutrons. It's fairly arbitrary but is illustrative of an area where judgment is essential.

Dr. David Kocher presented a graph representing the quality factor prepared by ICRU several years ago as he moved to a discussion of photons. He indicated where the reference radiation sat on the curve. The calculation showed that as energy decreased, the quality factor increased. The curve was used to infer over what energy ranges assumed REFs would apply. This was another instance where inferences had to be made based on information which could lead to different conclusions if only one dataset were used. Two sets of information were combined to come up with a 95 percent confidence interval for photons in the 30 to 250 keV range, based on non-human data.

For photons less than 30 keV, it was assumed that the quality factor from the ICRU curve described an increase relative to the intermediate energy photons. It was assumed that the correction was energy independent. The correction was described by a triangular probability distribution.

Regarding electrons, there exists a wealth of data on the biological effectiveness of beta particles from tritium decay, but virtually nothing on any other kinds of electrons. The energies of electrons from tritium decay are very low, so there was a curiosity about the biological effectiveness at higher than an average energy of about 6 keV. Using what is known about how photons interact to make inferences about electrons, it was assumed that the tritium data would apply at any energy less than 15 keV and this was applied to average beta energies or energies of discrete electrons less than this.

Dr. David Kocher reported a number of unresolved issues related to each radiation type, including validity of inverse dose rate effect for neutrons and alpha particles, as well as a lack of data in specific areas. Speculating on what might be developed in the future; Dr. Kocher opined that some dose reconstructions might ultimately need REFs for protons and heavy ions, including recoil nuclei and fission fragments.

NAS Report on Review of DTRA Dose Reconstruction Program

Mr. Dennis M. Schaeffer, Defense Threat Reduction Agency Department of Defense

Mr. Dennis Schaeffer presented an overview of the recently-released report of a study on the Defense Threat Reduction Agency's (DTRA) dose reconstruction program conducted by the National Academy of Sciences (NAS). The study was commissioned two and a half years ago as a result of a Congressional mandate following a General Accounting Office (GAO) audit of the program. The program started in 1978 under the DTRA's predecessor agency, the Defense Nuclear Agency. A major focus of the study was to determine if continuous oversight should or should not be implemented in the program.

The study encompassed a sample of 99 dose reconstructions performed by DTRA, primarily by its contractor, Science Applications International Corporation (SAIC). There had been three issues over the life of the program: (1) is dose reconstruction a valid process, (2) how does it help in working with a compensation program, and (3) is there sufficient benefit of the doubt exercised to give the veteran the best chance for compensation.

The Academy was given four charges associated with dose reconstruction specifically and one that related to the program as a whole. As relates to dose reconstruction, they were to determine: (1) if the reconstructed doses are accurate, (2) are the doses, as they are reported to the veterans and the Department of Veterans Affairs, reported accurately, (3) are the assumptions reasonable and credible with respect to estimating upper-bound doses, and (4) are the data, the records and historical reports, robust enough to allow dose reconstruction to be conducted and conducted accurately.

The Academy found that for external doses, the average value may be accurate and valid, although the upper-bound estimates in some cases may not be representative of the 95th percentile. For the most part, internal dose are representative upper-bound estimates. However, possibly severely underestimated are instances where doses are reconstructed for areas where fallout on the ground

from a previous test is impacted by shock wave of a current test and resuspension of previous fallout is not fully addressed?

While the Academy found that the doses reported to veterans and the VA are accurate, it was felt that a better job could be done of communicating upper bound uncertainties and what it means, and that the VA could improve communicating the actual risk in terms of cancers and other diseases.

In assessing whether assumptions are credible and reasonable the Academy found that scientific techniques available today to do uncertainty analysis on the 95th percentile value are not being taken into account. In the non-scientific area, in every case all the veteran could provide by way of personal anecdote and information was not incorporated consistently across the life of the program.

The Academy determined that the data are accurate and robust enough to support dose reconstruction, and that reference sources are sufficient and adequate to allow dose reconstructions from available historical data.

In assessing the overall program and determining whether oversight independent of the Agency is appropriate, the Academy found it was. Mr. Dennis Schaeffer indicated the Agency intended to look to do implementing oversight very much the same manner as is being done under EEOICPA in order to improve their program.

Mr. Dennis Schaeffer reported that he considered the Academy's investigation to be a very thorough a scholarly piece of work which will take their 20-year-old program into the future.

Discussion Points:

- Dr. Paul Ziemer noted that since this item was a late addition to the agenda due to the report's very recent release, Mr. Schaeffer was not in a position to go into great detail about the Academy findings, but perhaps Dr. John Till, the Academy's committee chairman, could be invited to address the group and go into the report in depth.
- Dr. Genevieve Roessler commented that it appeared the report was an indicator that the Board should continue its monitoring efforts in the future.
- Dr. James Melius asked what Mr. Dennis Schaeffer considered the most important findings. Mr. Dennis Schaeffer replied that procedural issues were an area where a lot of effort needed to be concentrated, but it provided a good opportunity since actions can be instituted right away.
- Dr. James Melius asked if any thought had been given to how to address the communication issue. Mr. Dennis Schaeffer responded that it remained to be developed the exact processes for extracting all the information from the veterans.
- Mr. Larry Elliott announced that the Board had been provided with the executive summary and title page of the report, and the public could find a pre-publication copy on the web site, www.map.edu.

- Mr. Mark Griffon asked about the apparent inconsistency in the Academy's conclusion that 20 of 99 exposure profiles had inadequacies, yet the data was overall adequate. Mr. Dennis Schaeffer pointed out that the report had to be read in its entirety to understand how it relates to the overall conclusion.
- Mr. Mark Griffon inquired if DTRA had an interview process. Mr. Dennis Schaeffer responded that there was an interview process, with various inconsistencies over the life of the program. A standard questionnaire is used, but not a scripted interview as done by NIOSH/ORAU.
- Dr. Antonio Andrade wondered how the GAO had the scientific basis to make its conclusions. Mr. Dennis Schaeffer replied that the GAO had said the body of knowledge as known today was not taken into account.

Public Comment Period

Mr. Richard Miller Government Accountability Project

Mr. Richard Miller pointed out that if, as Mr. Larry Elliott had indicated, the question of worker studies would be taken up after BEIR VII, and if BEIR VII is not released for two years, it could be five years past enactment of the statute before NIOSH looks at worker studies in its compensation model. He proposed the Board not wait for BEIR VII to look at the issue.

Next Mr. Richard Miller noted that claimants were faxing him letters from DOL stating that the probability of causation in chronic lymphocytic leukemia is zero. He asked the Board and NIOSH to consider opening the inquiry on that issue because he didn't believe it was defensible to say there is a zero probability of causation from any radiation exposure.

Ms. Denise Brock United Nuclear Weapons Workers of St. Louis, Missouri

Ms. Denise Brock shared the history of Mallinckrodt's role in the Manhattan Project and the ensuing dangers from that work. She reiterated issues raised previously related to the waiting period for completed dose reconstructions for people who are dying, as well as the issues of smoking and cancer and adding Mallinckrodt to the SEC. The inability of claimants to answer questions on the claimant questionnaire and their fear that if they said they didn't know the answer it would negatively affect their dose reconstruction was raised. She inquired into the completion of the Mallinckrodt site profile. She raised a question of workers under Q clearance whose records have been destroyed and who had multiple job titles with multiple exposures and how those issues would impact dose reconstruction. She confirmed her understanding of the impact of the proposed shortened latency period for bone cancer.

Mr. Phillip Foley PACE, Paducah, Kentucky

Mr. Phillip Foley expressed concerns about dose reconstruction because what had placed Paducah in the SEC was the questionable data. He pointed out that while there is a lot of data available; much was taken at the wrong time after exposures. He noted that one reason many workers don't know what they were exposed to is because they were told it was a national security issue and they didn't need to know.

With no further comments, the Board officially recessed until the following morning.

Tuesday, May 20, 2003

Dr. Paul Ziemer called the meeting to order at 8:00 a.m.

Ethics for Special Government Employees

Ms. Paula Kocher, Deputy Legal Adviser Office of General Counsel, CDC Department of Health and Human Services

Ms. Paula Kocher reminded the Board that with the responsibilities outlined in their Charter, came two sets of rules. A requirement to follow a standard of conduct as a SGE prohibited their accepting gifts because of their position or sharing non-public information. For those with a financial interest in matters which come before the Board, steps must be taken to avoid a conflict of interest. A second set of rules derived from the Federal Advisory Committee Act (FACA) is reviewed on a videotape provided by Ms. Paula Kocher to members of the Board, and includes a historical perspective about the Act.

The overriding purpose of FACA is to make as transparent as possible the consensus advice to the Federal government from people outside the government. It's the reason notices of meetings are posted, minutes kept and the meetings are open to the public.

Ms. Paula Kocher indicated that communications between Board members outside the public forum are permitted to exchange factual information. Even the appearance of conducting Board business or deliberating should be avoided when not at the table with a Federal official present.

Ms. Paula Kocher defined what is meant by a SGE and noted that one of the most important rules had to do with conflicting financial interests, although a waiver may be obtained if the Department determines that the need for service is greater than the conflict. Ms. Paula Kocher presented a number of examples to illustrate her points. Occasional gifts are acceptable if valued under \$20 and

the aggregate does not exceed \$50 from one source in a year.

Ms. Paula Kocher indicated that some issues may arise which are not so clear, in which event she urged Board members to contact Mr. Larry Elliott, Mr. David Naimon or Ms. Liz Homoki-Titus for clarification. She reviewed issues of use of non-public information and outside activities, as well as compensation, employment restrictions and post-employment restrictions.

Moving to rules imposed under FACA, Ms. Paula Kocher noted that it was important to remember that FACA promotes open and public meetings. Even meetings which are closed because of deliberation on non-public information have to be announced, and all documents made available or prepared for the Board must be available for public inspection and copy. Minutes of each meeting must be kept and the Chair must review and certify the minutes for accuracy. Advisory committee meetings may not be held except at the call of or with the advance approval of the committee's designated Federal official.

The Privacy Act was addressed briefly. Ms. Paula Kocher noted that Privacy Act rules were also applicable to SGEs, outlining them briefly, and providing examples of situations which could arise and how they might best be handled.

Ms. Paula Kocher indicated that web site accessibility makes Freedom of Information Act requests less necessary, but noted that the Department does answer all written requests for records. She suggested media and Congressional inquiries be directed to Mr. Fred Blosser of NIOSH and Mr. Larry Elliott, respectively.

Discussion Points:

- Dr. Paul Ziemer inquired whether travel expenses could be paid when a Board member is invited to speak about the Board's work at an out-of-town meeting. Ms. Paula Kocher replied she would have to check the travel regulations and get back to the Board with an answer.
- Mr. Larry Elliott advised the Board that because Ms. Paula Kocher's slides were somewhat difficult to read, they would be provided by e-mail later.

Epidemiological Research of DOE Workers - Status

Dr. David Utterback, Chief Health-related Energy Research Branch, NIOSH

Dr. David Utterback addressed the group on the background of the Health-related Energy Research Branch (HERB), indicating the core of the mission is to conduct analytic epidemiologic studies which conducted through both intramural and extramural research programs. The balance varies from year to year. About one-third of their funds have been awarded extramural research grants, contracts and cooperative agreements, which is felt to be an important way to allow the broadest range of intellects to address very complicated problems.

Annual funding over the years, since HERB's inception in 1991, has been approximately \$5 million, although for the last couple of years it has been substantially below that amount. There are currently 27 full-time employees within the Branch to operate and maintain the program.

HERB came into existence as a result of the determination that epidemiologic studies should be made independent of the DOE, so the decision was made to transfer the responsibility to the DHHS, where NIOSH does the occupational studies. Considered to be very important were issues of public trust, scientific quality, independence of investigators, stakeholder input, and an open process. The studies go through peer review, and CDC has recently instituted a policy that every five years research projects must go through another round of peer review.

The scientific staff is made up of industrial hygienists, health physicists and epidemiologists who conduct research within the group of studies. There is a staff of information technologists who deal with the tremendous amount of data, data manipulation, testing and evaluation required for the studies to be successful, as well as a support staff.

Dr. David Utterback explained that the research purpose was to understand radiation cancer risk factors in occupational cohorts, to evaluate the significance of health outcomes in radiation exposed workers, and to inform workers, the scientific community and the public of the health risks associated with exposures to radiological, chemical and other stressors. Research goals include evaluating the relationship between workplace exposures and diseases by using and applying the best available analytical methods.

Dr. David Utterback noted that the previous day he had heard in a discussion the issue of trying to get populations large enough for statistical analysis to be meaningful. He pointed out that at HERB they had combined studies across sites to obtain sufficient numbers to determine if an effect is associated with an occupational exposure. He explained it was not a simple task, but they had become specialists at it.

The group is working to address multiple exposures, exposures to radiation in combination with other chemicals, chemicals in combination with other factors and workplace stressors. This requires very large datasets and systems, and a considerable amount of time to accomplish. Their bottom line is to complete the epidemiologic research to increase understanding of the effects of low levels of exposure of DOE workers and others to ionizing radiation in the workplace.

Dr. David Utterback indicated that the purpose of his presence at today's meeting, along with Dr. Mary Schubauer-Berigan, was to talk about the status of the HERB program and how it fits into the questions the Board had raised in previous meetings. To that end they would be discussing the

uncertainty in the current knowledge, and to further identify any research areas the Board may have related to the compensation.

Dr. Mary Schubauer-Berigan, Lead Epidemiologist Health-related Energy Research Branch, NIOSH

Dr. Mary Schubauer-Berigan described cohort and case control studies currently being conducted through grants, contracts or cooperative agreements. These include a cohort study of Rocky Flats workers; the Hanford cohort mortality experience; a radon, cigarette smoking and their interaction on lung cancer risk at the Fernald facility; a study to evaluate time-related factors in evaluating cancer risk primarily restricted to the Oak Ridge National Laboratory (ORNL) cohort. This study is looking further into some of the issues regarding age at exposure and time since exposure and how to model complex epidemiologic data to disentangle the effects of time-related factors. A study looking at time-related risk factors and occupational radiation risks at the Savannah River Site cohort was just recently funded.

There are several internal studies ongoing at the Portsmouth Naval Shipyard. While not a DOE facility, it is primarily a group of workers who were exposed to high energy photons, offering an opportunity to study issues related to that particular exposure. It is a classic occupational setting in which exposures are received chronically rather than acutely. Several reports are soon to be issued for that cohort.

A large cohort study is underway for a group of more than 60,000 workers at the Idaho National Engineering and Environmental Laboratory (INEEL). This is a very diverse work force consisting not only of radiation workers, but workers who may have had more incidental access to the site. There are also workers who were involved in the construction of the facility. A final report is expected before the end of September for this cohort.

A third cohort-based study is of the chemical laboratory workers at four facilities within the DOE complex, the three facilities in Oak Ridge and workers at the Savannah River Site. This study will address issues with regard to interactions between chemical exposures. Of primary concern are workers employed in inorganic, organic, and organic mist labs. This study is expected to be completed before the end of the calendar year, perhaps in late winter.

A cohort study of Fernald workers has been driven by questions related to uranium exposures. It is expected to also address issues related to radon and lung cancer. This study is in its early phases and not expected to be completed for several years.

Dr. Mary Schubauer-Berigan explained the difference between cohort and case-control studies, and outlined several case-control studies currently ongoing to address specific questions. These include a leukemia case-control study in the Portsmouth Naval Shipyard, which is near completion. A second case-control study at the facility is looking at lung cancer risk. This was driven by

observations in the first studies conducted in this cohort in which excess risk of lung cancer was observed. Because of high asbestos exposures and possible exposures to welding fumes at the facility, the need to do a lung cancer case-control study to evaluate those three factors in addition to smoking was anticipated. This study is approximately a year and a half from completion.

Ongoing for several years is a multi-site leukemia case-control study combining workers from six different cohorts at five different DOE and DOD facilities, including Hanford, Savannah River Site, Los Alamos, the ORNL, and the Portsmouth Naval Shipyard. The study has almost 260 cases of leukemia, making it one of the largest studies of its type ever conducted. It is also looking at the potential to evaluate plutonium dose to the bone marrow for workers, particularly at Oak Ridge, Savannah River Site, Hanford, and Los Alamos.

A very large case-control study of multiple myeloma in K-25 workers follows a previous investigation of multiple myeloma across the DOE complex. The study hopes to explore further some of the important exposures, particularly to internally-deposited uranium and multiple myeloma risk.

A multi-site lung cancer case-control study which had been underway is now on hold due to other higher priority studies. A health physicist has not been assigned to the project, but it is being worked on from an epidemiologic and industrial hygiene perspective. The study is quite complex in that it is studying a number of facilities across the complex and attempting to get around the issue of confounding by restricting itself to workers in the reactor areas. It is hoped that the exposure assessment for that group of workers would be simplified.

Dr. Mary Schubauer-Berigan noted that virtually all these studies have to take into account not only radiation exposure, but exposures to other factors which could be confounders, somehow obscuring the relationship between radiation risk and cancer. In many of the studies not only is evidence of confounding looked at, but also effect modification or interaction.

Looking to the future, Dr. Mary Schubauer-Berigan shared with the Board the establishment of HERB Epidemiological Database System (HEDS), the HERB Epidemiological Data management System. HEDS is a complex database of DOE and Department of Defense (DOD) workers, all of which have been studied by HERB in some way, containing demographic and work history data and radiological exposure data. It also contains non-radiological exposure data such as chemical exposures or physical hazards other than radiation, anything measured which isn't related to radiation. The data are linked by a master roster, so that each time a new cohort is entered into HEDS, it must be matched against everyone already in there, allowing workers who went from facility to facility to be located. It allows multi-site studies and the taking into account of exposures across the complex. Key staff of this project is comprised of information technologists, with input from epidemiologists, exposure assessors and others.

HEDS is an integral part of future high priority projects because it will allow more multi-site studies

to be conducted since it is believed it will provide the power to overcome the problem in doing low-dose chronic radiation epidemiology studies. Cohort-based studies being considered include neutron-exposed workers across the complex. At present there are no human cohort studies of neutron exposures and risks directly from neutrons. Also anticipated is studying plutonium across the DOE complex. The most effective way to do so is to combine plutonium exposures through HEDS and be able to evaluate, complex-wide, the hazards of plutonium exposures. Of slightly less priority are anticipated studies of uranium-exposed workers. Tritium and polonium exposure-based cohort studies have also been discussed.

Dr. Schubauer-Berigan noted that most of the studies have been of cancer mortality because those data systems are well established for epidemiologic research and their use is understood. It is recognized that these systems are not as efficient for studying cancer incidence for disease with low mortality rates, which is believed to be important. Because the U.S. doesn't have a good system for monitoring cancer incidence on a nationwide basis, it's difficult to find comparison statistics across a population or even incident cancer cases in a defined population. The development and evaluation of such an incidence study system is viewed as a high priority and is being looked at currently.

Current worker exposures and health effects are of great interest from a public health standpoint. As facilities move into a decommissioning and decontamination era, studies of hazards faced by these workers is an important future direction.

Addressing Board priority items identified at the previous meeting, Dr. Schubauer-Berigan indicated that many of the current studies will provide valuable data in those areas. In particular she noted that to incorporate occupational studies into risk models, it is important to establish an occupational gold standard against which risk coefficients could be based and evaluated, much as the A-bomb survivor data is considered the gold standard for acute exposures. Also described were some issues not included among the Board's priorities but which had been raised in the past and are considered important.

In conclusion, Dr. Schubauer-Berigan spoke about issues regarding current workers, noting that problems didn't end with the end of the production issue. Some of those issues have been identified and are outlined in some of the documents to be found in the annotated bibliography provided. They include the possibility that decommissioning and decontamination workers could not only face different hazards in the workplace, but different health effects. Outreach efforts are underway to current workers to identify issues of concern to them. Gathering this information will help develop future research that could help address those issues. The collection of quality important concerns are being heard regarding adequacy of radiation monitoring and health monitoring among current workers, particularly among subcontractors who may not have access to the same level of monitoring as prime contractors at a facility. Information quality that could support future epidemiologic studies and compensation practice is of some concern.

Discussion Points:

- Dr. Paul Ziemer asked for an explanation of the difference between analytical epidemiological studies and descriptive epidemiological studies. Dr. Mary Schubauer-Berigan defined a descriptive epidemiological study as one that attempts to define disease in terms of where and when it occurs. An analytic epidemiology study looks at the level of the individual and tries to evaluate associations between disease and some kind of exposure.
- Dr. Paul Ziemer asked for a description of the Comprehensive Epidemiological Data Resource (CEDR). Dr. Mary Schubauer-Berigan explained that CEDR contains deidentified information containing analytic files used to conduct epidemiological studies and is operated by DOE through contract with Lawrence Berkeley.
- Dr. Roy DeHart inquired into the interface between HERB and ongoing medical evaluations with non-DOE workers who were contract workers at DOE facilities. Dr. Dave Utterback responded that there are currently 15 or 16 programs underway and HERB does interact with the group.
- Dr. Paul Ziemer queried HERB's access or use of the database from the U.S. Transuranic Registry as regards plutonium workers. Dr. Dave Utterback indicated that information had not been used within internal HERB studies, but had been through an external investigator.
- Dr. Ziemer inquired into collaborations relative to Chernobyl workers. Dr. Dave Utterback indicated that an extramural grant was addressing that issue.
- Mr. Owens wondered if there had been a completion date contemplated for the Paducah study by the University of Kentucky and University of Louisville because the union had been directly involved initially. Dr Mary Schubauer-Berigan indicated she had not recently seen a projected end date, but cautioned that it was a large undertaking and could take some time. Dr. David Utterback added that some business aspects were being worked through, including issues of pertinent records stored in a vault in a secure area where access requires clearance, which takes time these days.
- Mr. Griffon inquired into the possibility of integrating past and present studies into the items of interest to the Board as a starting point for modification of uncertainty estimates in the IREP model. Dr. David Utterback responded that he saw that as an initial step in some of the research goals, but it was an analytical process to do that and a worthwhile one, which was being looked at to address in the future.
- Dr. Ziemer asked how HERB investigators are using DOE dose data which has been called inadequate and making it adequate for their studies with confidence that the final result is useful. Dr. Utterback responded that he would prefer to come back before the Board to address that at some point in the future. Dr. Schubauer-Berigan added that many epidemiologic studies put exposures into bins, and there are many methods incorporated to try to do that.
- Mr. Mark Griffon wondered if HERB had access to OCAS records. Dr. Mary Schubauer-Berigan replied that at many levels there is a lot of interchange between HERB and the work being done by OCAS. Mr. Larry Elliott added that information received from claimants and interviews under the Privacy Act system of records could be accessed by HERB, in an institutional review board-approved protocol study, if the study designed called for it and

was approved.

Board Discussion/Working Session

Review Process of Completed Dose Reconstructions

Mr. Mark Griffon briefly described each of six documents developed by the workgroup, copies of which were provided to the Board, and explaining their intended purpose. He suggested the Board members review the documents prior to the next meeting and be prepared for a full Board discussion and development of a final draft at that time. Dr. Paul Ziemer suggested that everyone who had a copy of the documents, including the public, mark them as working drafts to avoid future confusion

Dr. Andrade asked for an explanation of the statement "numbers will be provided to NIOSH", inquiring who would provide the numbers. Mr. Mark Griffon indicated that, language notwithstanding, the intent was that the Board would select the case numbers using a random stratified approach, at which time the numbers would be provided to NIOSH so those records could be pulled.

Mr. Larry Elliott pointed out that he didn't have an answer to Privacy Act questions at this time because NIOSH needed to understand what the Board was proposing to do and how the process looked before they could address how they would control Privacy Act-related information.

As Mr. Griffon continued to review the documents, the issue was again raised of interface of the Board and contractors with relevant experts and the individual claimant and his desire to do followup interviewing. Dr. DeHart indicated it was his understanding that the Board's access to the records would be post-adjudication. Mr. Elliott agreed, noting that the Board's review of completed dose reconstructions was review of the pool of cases which had reached final adjudication. The issue of clearance was discussed in the follow-up process, with Mr. Elliott indicating that included a classified member of the Board.

Dr. Antonio Andrade suggested that perhaps the draft task orders be turned over to either the project officer or the contracting officer for drafting so that they could be reviewed in near-final form, then proceed to comment and work on them at the next meeting. Dr. Paul Ziemer agreed, but noted that Mr. Mark Griffon had suggested he work with Dr. James Neton in terms of language necessary to meet Federal requirements.

Dr. Paul Ziemer expressed a concern that the Board consider dealing with the issue of interviews in a way that would not hold up the process. He cautioned that closed cases should be considered very seriously in terms of what that means to a claimant, whether successful or unsuccessful, because it is already known that the interview process has been rather traumatic in some cases and he questioned

what was to be gained by it. Mr. Larry Elliott was in full agreement with Dr. Paul Ziemer's comments and added that the audit should be conducted looking at the informational materials supporting the decision. He noted that if issues associated with the interview process were identified, that may trigger a need, although he was not in a position to say there would be the ability to interact with claimants due to the vast number of issues associated with that post-decision. He indicated that it was the opinion of NIOSH that the documentations supporting the interview interaction with claimants was what the Board should review and evaluate for quality and credibility.

Mr. Mark Griffon countered that alternatives to re-interview were not being done, such as transcribing or taping the interviews and that one of the Board's roles is to make sure that part of the process is done in an adequate fashion. Dr. Antonio Andrade pointed out that the Board's findings should be used to improve the process, and in that sense they are conducting a forward-looking type of audit. Deficiencies found should be pointed out to NIOSH for improvement in the future and that going back retroactively would be a mistake. Mr. Robert Presley suggested that between NIOSH and the attorneys, some language could be developed that left the door open for the Board to make a request for an interview if it saw fit.

Dr. Roy DeHart raised the question of the necessity of training of Board members, such as use of the data access system, in order to work with the contractors. The Board decided to keep that in mind for future discussion.

Public Comment Period

Mr. Carl Scarbrough, President Atomic Trades and Labor Council Oak Ridge, Tennessee

Mr. Carl Scarbrough made an appeal to the Board for fairness. He indicated that one of the most difficult things is the expectation of the claimants that they're going to be compensated, justifiably or not. He asked that everyone in the process look at claimants not as numbers, but as if they were members of their own family.

Mr. Robert Tabor Fernald Atomic Trades and Labor Council

Mr. Robert Tabor agreed with Dr. Mary Schubauer-Berigan's presentation relating to decommissioning and decontamination era workers because Fernald is a site in full blown closure. He expressed his concern related to information relative to D&D employees and future availability of that information. He asked for government assurance that the information could be retained, citing a recent memo which indicated that the current contractor is fully in charge of all current information. He expressed his belief that information retention is a serious issue at sites that now have a short life.

Dr. Owen Hoffman SENES Oak Ridge, Inc.

Dr. Owen Hoffman expressed his concern that there is an organizational disconnect between the occupational safety program and the needs for epidemiological research, noting that HERB is funded by the DOE under a Memorandum of Understanding (MOU), but with no constituency, no mechanism for assessing the adequacy of the funding, whether the spirit of the MOU is being honored, et cetera. He wanted to publicly express his concern for whether the studies are sufficiently funded to ensure that the answers come forward in a timely manner.

Dr. Owen Hoffman reminded Dr. Genevieve Roessler of her presentation to Congress two years ago indicating there was no epidemiological evidence to support risk below 10 rem effective dose, and asked her if there is support for this in light of new epidemiological evidence coming forward. Dr. Genevieve Roessler responded that if she were making that presentation next week, she would do as she had done then and do research to find the appropriate number.

Mr. Mark Griffon inquired if Dr. Owen Hoffman had an answer to his own question. Dr. Owen Hoffman replied that in terms of a constituency or mechanism to ensure preservation of the MOU, the answer is no, it needs to be rebuilt. In terms of evidence for risk below 10 rem, he believes it exists. Dr. Mary Schubauer-Berigan pointed out that was why it was important to design studies carefully and to combine cohorts to increase the statistical power to see low effects that might be expected at doses in the range of 1 to 10 rem.

Mr. John Stewart, Safety Representative **PACE**

Mr. John Stewart indicated that he'd heard enough technical information and shared some anecdotal information about some of his coworkers and their experience with exposure, illness and record availability. By way of illustration, he recounted a situation in which a current worker diagnosed with cancer filed a claim under EEOICPA and was told by DOE there was no record of his ever having worked at a DOE facility. His question was directed toward how something from 40 years ago can be located if current employment records can't.

He noted that only two weeks ago the President had declared fighting was over in Iraq and Iraqis are now being paid benefits, while workers suffer financial hardship as a result of their employment and can't get compensation. He commented that workers feel as if every aspect of their lives is being studied, their records, their health, how much radiation it takes to cause their cancers, while they're dying and not getting compensated for it.

Mrs. R. L. Ayers, Survivor Oak Ridge, Tennessee

Mrs. R.L. Ayers, whose husband had died of silicosis, inquired if sites in Tennessee would ever be added to sites in Alaska and Nevada, the only states currently compensable for that disease, since her husband had never been in either state. Mr. Pete Turcic from DOL confirmed that only individuals involved in mining tunnels for underground test sites at Amchitka in Alaska or the Nevada Test Site were covered. He directed Mrs. Ayers to Subtitle D of EEOICPA which relates to other toxic diseases, including silicosis, to get State Worker's Comp.

Mr. Stewart added that silicon sand had been used to blast tubes during the centrifuge program and that probably everyone at K-25 had been exposed to the dust. He pointed out that with 16,000 waiting to see a panel doctor it could take 20 years for that visit.

Board Discussion - Non-Agenda Item

Mr. Larry Elliott raised an issue with the Board, stating that it went at the heart of appearance of conflict, but wanted to get a sense of where the Board stood. There are several individuals with ORAU who were integral in the development of prior dose reconstructions for the Mound, Ohio site. Mr. Larry Elliott wanted to be able to ask ORAU to task those individuals with individual dose reconstructions in an effort to achieve the completion of 6,000 completed dose reconstructions against the backlog by the end of the year. He would like to ask experts on his staff from Fernald to work on Fernald cases. This would not remove the claimant's ability to object and request another individual be assigned, which would provide sufficient control and protection against appearances of conflict of interest.

Dr. Antonio Andrade felt that for all the reasons given by Mr. Larry Elliott, particularly efficiency and the built-in expertise, it would be a waste to not use those people who could get the process moving at a faster rate. He reminded the Board that the auditing process being established by the working group includes people who may never have worked at these sites. This helps in going back to check fairness, so that checks and balances are in place and he considered the suggestion an excellent one.

Ms. Wanda Munn noted that failure to take advantage of known expertise can only lengthen the process. If there is a perceived concern with respect to trustworthiness of reviewers, it could be met with a statement of recusal. There is an issue of institutional knowledge that cannot be rapidly accumulated by other individuals which it would be a shame to lose.

Dr. Henry Anderson indicated that he believed it important to uniformly apply the protections against conflict of interest and bias already set up. While some flexibility might be helpful, he felt the developed criteria should be adhered to, but that it was really up to NIOSH to decide. Is the

balance greater one way or the other. Perhaps if the dose reconstructions were part of a research project it might be different.

The issue of conflict versus appearance of conflict of interest was discussed, and some members indicated that it was their understanding those people could be used as resources so that their expertise would not be lost, as in developing site profiles. The shortage is in dose reconstructors and reviewers to get cases processed using those site profiles. Mr. Larry Elliott pointed out that each finished case is reviewed by his staff, and that he personally reads and signs every one and considers the controls to be in place. Dr. James Neton added that ORAU has taken the conservative approach that since MJW did all the dose reconstructions at Mound, no one on their staff or employed by MJW could do a dose reconstruction at Mound. Dr. Paul Ziemer confirmed that was a very broad interpretation of conflict.

Mr. Mike Gibson was in complete opposition, stating that he had questioned the results of those dose reconstructions at the time they were done. He pointed out that since he had had to go through an interview with the President's general counsel for a waiver of conflict of interest and agree to recuse himself from any issue dealing with Mound, he had a problem with allowing people who had made millions of dollars at the site redo dose reconstructions they've already done.

Dr. Paul Ziemer noted that from a cross-section of views, there was no real consensus. He indicated that Mr. Mike Gibson's experiences seemed pertinent, although he would not have personally objected to individuals simply because they worked for the company if they had not worked on the site. Public comment was suggested and agreed to, keeping in mind there was a tight schedule.

Mr. Richard Miller Government Accountability Project

Mr. Richard Miller opined that the issue should have been brought up prior to the public comment period and suggested the matter be put on the agenda for the next meeting. He pointed out this was not a newly-discovered problem just encountered by NIOSH. He suggested putting the question of conflict onto the claimants, who don't remember names or know who did dosimetry and who worked in large facilities, is putting it in the wrong place. He further questioned the adequacy of the conflict of interest screening.

Mr. Richard Miller proposed expanding the pool of people, authorizing ORAU to bring in others who don't have conflicts of interest, allocating more money if there wasn't enough budgeted to solve the problem, but not to tear down the conflict of interest wall.

Review/Approval of Minutes

Motions

Dr. Anderson moved to approve the executive summary and minutes of the Eleventh meeting. Dr. DeHart seconded. The motion received unanimous approval.

Mr. Espinosa moved to approve the summary report of the Twelfth meeting. Mr. Presley seconded. The motion received unanimous approval.

ABRWH Schedule and Future Agenda Items

Motion

Mr. Presley moved the Board meet in Cincinnati on August 18, 19 and, if necessary, 20. Dr. DeHart seconded. The motion received unanimous approval.

Action will be taken on the materials provided by the Dose Reconstruction Review working group. A status report on site profile was requested and will be provided, if possible.

Housekeeping and Miscellaneous

Ms. Corrine Homer requested that in the future members provide by e-mail their time to Mr. Larry Elliott for approval, separating time for working group business and regular meeting time.

In an effort to plan a fall meeting, it was suggested that Board members provide their calendars to Ms. Corrine Homer through November.

Mr. Presley gave instructions to those members of the Board who planned to participate in the Oak Ridge tour.

Dr. Paul Ziemer noted for the public that the tour was simply an effort to allow Board members to see the site and learn more about Oak Ridge, and that no official business would be conducted on the tour.

With no further business posed, the meeting was officially adjourned at 1:50 p.m.

End of Summary Minutes

I hereby confirm that these Summary Minutes are accurate to the best of my knowledge.

